

REMARKS

Claims 6-9 and 20-29 (to methods where (A) is chlorogenic acid) are active. Product Claims 1-5 have been withdrawn from consideration, as have Claims 8 and 9 which are directed to methods where (A) is ferulic acid or caffeic acid. Claims 6 and 20 have been amended to refer to isolated chlorogenic acid (A) and further identify the particular heat components in component (B). Support for this amendment as well as for new Claims 21-29 is found in the specification on page 4, last two lines and on page 8, lines 4-23. Accordingly, the Applicants do not believe that any new matter has been added.

The Applicants express their appreciation to Examiner Coe for the courteous and informative interview of November 4, 2004. To address the indefiniteness, prior art, and the non-provisional obviousness-type double patenting rejections of record, it was suggested that the Applicants might direct the claim language to “isolated chlorogenic acid” and to specific isolated central nervous system stimulants (e.g., heat components) described in the specification. The claims have now been so revised. Favorable consideration and allowance of this application is now respectfully requested.

Rejection—35 U.S.C. § 112, second paragraph

Claims 6, 7, 10 and 20 were rejected under 35 U.S.C. 112, second paragraph, as indefinite. These rejections are moot in view of the amendments above.

Rejection—35 U.S.C. § 102

Claims 1, 7 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Hsu, U.S. Patent No. 5,958,417. The Applicants submit that Hsu does not anticipate the present claims, because it does not disclose or suggest compositions comprising isolated chlorogenic acid. Hsu is directed to *Crataegus* (hawthorn) to treat various diseases including

hypertension (col. 2, lines 55-63). While various “active principles” are enumerated by Hsu, this reference does not disclose compositions containing isolated chlorogenic acid, nor suggest that chlorogenic acid is the active component in *Crataegus* that ameliorates hypertension. Moreover, this reference does not disclose the specific CNS stimulating components now described at the ends of Claims 6 and 20. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. § 103

Claims 1, 7 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,958,417 and JP 63267255. Hsu has been addressed above and does not disclose or suggest methods that involve the administration of isolated chlorogenic acid, or isolated chlorogenic acid and a heat component.

Similarly, JP 63267255 does not disclose or suggest this combination. Moreover, JP ‘255 only discloses crude liquid extracts of ginger (“ginger juice”) obtained by grinding ginger leaves and stems which it alleges may be used for “depressing blood pressure” and “improvement of human constitution”. However, this reference provides no evidence that the crude ginger extracts actually lower blood pressure or that the heat components are involved in the depressing blood pressure. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. § 103

Claims 6, 7, 10 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al., Chin. Pharm. J. 46:575 and JP 63267255 (Abstract). The Applicants respectfully submit that this rejection would not apply to the present claims. The cited prior art does not disclose or suggest a method for treating hypertension using isolated chlorogenic

acid in combination with a central nervous system stimulating component(s) which is at least one isolated heat component of *Zingiberaceae*, *Capsicum* or *Piperaceae*.

While Cheng, page 579, Table 1, describes the effect of intravenous injection of chlorogenic acid on arterial blood pressure of spontaneously hypertensive rats, this document provides no suggestion to combine particular heat components with isolated chlorogenic acid.

JP '255 discloses crude liquid extracts of ginger ("ginger juice") obtained by grinding ginger leaves and stems which it alleges may be used for "depressing blood pressure" and "improvement of human constitution". However, this reference provides no evidence that the crude ginger extracts actually lower blood pressure or that the heat components in ginger are involved in the depressing blood pressure. Therefore, the Applicants respectfully request that this rejection be withdrawn.

#### Rejection—Obviousness-type Double Patenting

Claims 1, 7 and 20 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,458,392. The Applicants submit that this rejection should be withdrawn in view of the amendment of independent Claims 6 and 20 to isolated chlorogenic acid and isolated heat components. The claims of the prior patent are directed to combinations, such as soy sauce, containing isolated chlorogenic acid and caffeine. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

#### Provisional Rejection—Obviousness-type Double Patenting

Claims 1, 7, 10 and 20 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending U.S. Applications 09/922,694 or 10/826,289. While these two applications currently claim

methods of reducing hypertension, they are directed to methods involving ferulic acid and optionally, chlorogenic acid. However, the copending claims do not claim the combination of isolated chlorogenic acid and a heat component. Accordingly, the Applicants respectfully submit that these provisional rejections be withdrawn or held in abeyance pending the identification of otherwise allowable subject matter in the present application, see MPEP 804(I)(B).

Provisional Rejection—Obviousness-type Double Patenting

Claims 1, 7, 10 and 20 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending U.S. Applications 10/632,810 and 10/810,611, in view of JP 63267255. While some of the copending claims are directed to methods for treating hypertension, the copending claims do not claim a method of administering the combination of isolated chlorogenic acid and a heat component. Therefore, the Applicants respectfully request that they be withdrawn or held in abeyance pending the identification of otherwise allowable subject matter in the present application, see MPEP 804(I)(B).

Application No. 10/626,708  
Reply to Office Action of October 19, 2004

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, reading "Thomas Cunningham". The signature is written in a cursive, flowing style.

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